# PSJ3

# Exhibit 350

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Chronology of HDMA/HDA Executive Committee and Board of Directors' Drug Abuse and Diversion Discussions at Meetings/Conference Calls
January 2, 2018

**2012**

2/16/12 Executive Committee Meeting:
HDMA met with DEA staff in December 2011 in an effort to improve communications; brief discussion of DEA's actions against Cardinal and CVS; John Gray to testify in a hearing on March 1 to address prescription drug diversion at the invitation of Rep. Mary Bono.
EC asked OFW to prepare a draft amicus brief in the Cardinal case.

Regulatory Affairs
Ms. Anita Ducca (HDMA Vice President, Regulatory Affairs) provided an update on regulatory matters, including postponement for seven additional years of the DOT tote marking requirement; further engagement with DEA, including Al Santos (Deputy to Joe Rannazzisi) who will speak at the DMC and the possibility of a face-to-face meeting with DEA.

4/6/12 Executive Committee Conference call
President John Gray thanked Executive Committee members for agreeing to participate in a conference call to address recent activity with respect to suspicious order monitoring and the role of healthcare distributors. HDMA has testified before Congress and prepared an *amicus curae* brief for filing with the federal Court of Appeals in the *Cardinal v. Holder* litigation.

Chairman Moody and Vice Chairman Neu expressed concern about the trend of recent developments and thought it time for the Executive Committee to review recent events and plot a course for going forward.

President Gray reviewed recent activities and options for moving forward:

1) Partnership at Drugfree.org (formerly Partnership for a Drug-Free America) (PDFA). HDMA has been invited to participate in a program with the PDFA to study how government and industry can better manage the pharmaceutical supply chain to eliminate controlled substance diversion and abuse. PDFA has submitted a proposal for the first phase of the project, which was shared with EC members on 4/2/12.

Redacted

2) HDMA is sponsoring the National Governors Association Prescription Drug Abuse Reduction Policy Academy. This is a special project that NGA is undertaking to address the growing incidence of prescription drug abuse in the U.S. Redacted

3) HDMA is stepping up its efforts to educate the public, through the media, about the controlled substance supply chain and efforts being undertaken by distributors to prevent diversion and reduce prescription drug abuse.

4) President Gray reported that HDMA and OFW plan to meet with Rich Cooper, Esq. and Bob Bennett, Esq. of Williams and Connolly to discuss other potential means of engaging DEA to better understand and manage suspicious order monitoring efforts.

5) HDMA is coordinating its efforts with NACDS.

6/10/12 Executive Committee Meeting:

Prescription Drug Abuse, Diversion and DEA

Executive Committee members expressed satisfaction with HDMA's role in supporting industry efforts to gain greater clarity from DEA as to what is needed to comply with suspicious order monitoring requirements. Mr. Mike Kaufmann (Pharmaceutical Segment, Cardinal Health, Inc.) thanked Executive Committee members and HDMA for its support during its litigation with DEA. Mr. Kaufmann summarized an NACDS initiative which would rely substantially on SureScripts to electronically capture all controlled substance prescriptions and orders. NACDS is considering support for legislation which would require that all such prescriptions and orders flow through SureScripts or something similar. Challenges include opposition from the American Medical Association and the 27 states which currently do not permit electronic prescriptions.

Mr. Kelly reported that controlled substance related matters that have played a prominent role in the PDUFA process include Senator Manchin's (D-WV) language to reschedule hydrocodone combination products from Schedule III to Schedule II. HDMA is opposing the amendment. HDMA is looking for carve-out language for wholesalers should the Manchin amendment pass. Additional Congressional activity includes Representative Bono Mack's (R-CA) letter to the Secretary of the US Department of Health and Human Services and the US Attorney General seeking clear guidance from DEA on prescription drug diversion issues. Senators Grassley (R-IA) and Whitehouse's (D-RI) requested GAO report on DEA policies and their potential impact on drug

shortages. Finally, Senators Baucus (D-MT) and Grassley sent a letter to opioid manufacturers requesting information about financial contributions to entities supporting greater access to pain medicines.
President Gray reported that the $200,000 previously approved by the Executive Committee to work with the Partnership for a Drug Free America likely will be applied instead to other DEA related activities and he will keep them posted.

6/10/12 Board of Directors Meeting:

Prescription Drug Abuse and Diversion
Mr. Kelly provided an update on recent Congressional, DEA and court activities regarding prescription drug abuse and diversion. Senator Manchin (D-WV) has introduced an amendment to reschedule hydrocodone-combination products from Schedule III to Schedule II. This would create huge logistical problems for HDMA members. Other Congressional activities include the Representative Bono Mack (R-CA) letter to the Secretary of the Department of Health and Human Services HHS and the Attorney General of the United States seeking better guidance and communication regarding prescription drug abuse and suspicious order monitoring and the Baucus (D-MT)/Grassley (R-IA) letter to opioid manufacturers on marketing. HDMA continues to work with the National Governors Association seeking state level strategies and solutions.

Ms. Anita Ducca (HDMA Vice President, Regulatory Affairs) provided an update on DEA related activities. HDMA filed an *amicus curiae* brief in the *Cardinal v. DEA case.* . HDMA staff and counsel met with attorneys from Williams & Connolly to seek new ideas for engaging DEA and finding greater clarity regarding suspicious order monitoring requirements. Ideas include: (1) industry developing its own ARCOS-like data base; (2) develop customer algorithms and thresholds; and (3) third-party audits. Other ideas include enhanced communication activity, partnering with the Partnership for a Drug Free America, or establishing an organization similar to the beverage alcohol industry's Century Council. A proposal for addressing the communication challenges is expected shortly from the Rand Corporation.

Mr. Al Paonessa (Anda) urged greater engagement with controlled substance manufacturers. Mr. Mike Kaufmann briefly discussed the NACDS idea of utilizing SureScripts as a means of enhanced suspicious order monitoring.

Following extensive discussion, President Gray promised to review and organize the numerous program initiatives under consideration and to continue making this issue a top priority.

9/30/12 Executive Committee Meeting:

A Controlled Substance Abuse Task Force has been empaneled which is looking at federal, state and public relations issues. The GPPC and RAC recommend focusing first on public relations issues.

Mr. John Parker presented an update on the current state of play regarding how wholesalers are being portrayed in the media and their implications for HDMA members. The GPPC has recommended a strategy of education, advocacy and collaboration. The goal is to find a public relations firm to help execute the strategy. Proposals from APCO and GMMB will be made to the Board on October 1, 2012. Discussion ensued regarding the scope of a PR program and the possibility of handling some of this work with staff and member assets. No decisions or recommendations were made. PR firm proposals will be considered by the full Board and the Executive Committee and staff will put together a plan including HDMA staff, member, and third-party assets.

10/1/12 Board of Directors meeting:

Controlled Substances

Mr. Patrick Kelly reported on recent developments regarding controlled substances diversion and abuse. HDMA has convened a Controlled Substances Task Force which includes elements from the legislative, regulatory and public relations arenas. The GPPC supported development of a public relations strategy, working with an outside firm, to augment legislative and regulatory initiatives. Mr. John Parker introduced the public relations background. Mr. Parker discussed the current state of play and the support of the Controlled Substances Task Force to engage a public relations firm to assist with the campaign to better educate the public and decision makers as to what pharmaceutical distributors do. The focus will be on who we are and what we do to deliver life-saving medicine and recent controlled substance diversion and abuse. Two public relations firms were invited to present to the Board. It is anticipated that the public relations element will work on coordination with government affairs, regulatory and members resources. The following public relations firms presented:

GMMB – Dr. David Mitchell and Ms. Christine Glunz
APCO – Mr. Michael Tuffin and Mr. Robert Schooling

Following the two presentations, discussion ensued. Interest was expressed in ramping up the public relations initiative with a firm, member assets, and Association staff. Some concern was expressed as to whether the initiative could "move the needle" and persuade DEA to work cooperatively with distributors as opposed to adversarially. There was discussion regarding how much of the proposed scope of work HDMA should engage a firm to do.

Action: ...the Board approved retaining APCO to assist with the public relations initiative, with the budget and details to be worked out by the Executive Committee and staff.

Redacted

11/16/12 Executive Committee call:

COMMUNICATIONS INITIATIVE ON PRESCRIPTION DRUG ABUSE AND DIVERSION (Phase I Proposal Circulated with Executive Committee Materials). Mr. John Parker (HDMA Vice President, Communications) briefly discussed the elements of Phase I of APCO's proposed strategic communications effort to address prescription drug abuse and diversion with a focus on the contributions made by distributors. APCO proposed qualitative and quantitative research designed to arm HDMA with the appropriate resources to identify threats, mitigate risks, educate primary stakeholders and build the foundation for a leadership platform. The research phase would last approximately three months with findings to be shared with the Executive Committee at its next meeting on February 22, 2013. Redacted

Discussion ensued. Executive Committee members asked that APCO's efforts be coordinated closely with efforts from communications firms currently being utilized by individual members. Mr. Mike Kaufman (Cardinal Health, Inc.) suggested the RAND initiative also be considered and noted that individual members may want to fund that program. President Gray will recirculate the RAND proposal for discussion.

Redacted

**2013**

2/22/13 Executive Committee Meeting

PUBLIC RELATIONS RESEARCH REPORT. Mr. John Parker (HDMA Vice President, Communications) provided a brief background on Phase 1 of the public relations project and the selection of APCO to be the public relations partner. Mr. Michael Tuffin (Managing Director, Washington, DC, APCO Worldwide) introduced the work to date, which involved mostly research of opinion leaders and views of thought leaders about the problem of controlled substance diversion and abuse and the roles played by doctors, clinics, distributors, manufacturers and government. APCO conducted a series of focus groups and interviews, looking at who opinion leaders blame for drug abuse and diversion and possible solutions. Quantitative research will focus on what messages and platforms may be effective to publicize the extensive efforts made by distributors to address the problem. APCO recommended that HDMA be a primary resource in getting the story out and helping respond to crises.

Phase 2, scheduled from March to December 2013, will involve an educational program, developing messages for crisis and rapid response, creating communications tools for this program, educating target stakeholders and speaking at relevant events.

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6/2/13 Executive Committee Meeting

APCO
John Parker (HDMA Vice President, Communications) gave a brief overview of his planned presentation to the Board regarding the ongoing APCO project on improving public relations with regard to prescription drug diversion.

6/2/13 Board of Directors Meeting

APCO Project Update
Mr. Gray and John Parker (HDMA Vice President, Communications) presented an update of the ongoing APCO project on improving public relations with regard to the role of the distributor in helping curtail prescription drug diversion. Study findings to date indicate that primary distributors rank very low on the "who's to blame" list for prescription drug diversion and misuse.

9/30/13 – Board of Directors Meeting:

Controlled Substance Abuse and Diversion. Mr. Patrick Kelly (HDMA Senior Vice President, Government Affairs) provided an update on legislative and regulatory

activities concerning controlled substance abuse and diversion. The CSA Task Force has developed a "Guiding Principles" document. Legislation being developed in the House by Representatives Tom Marino (R-PA) and Marsha Blackburn (R-TN) addresses/advances HDMA interests. The legislation would define "imminent danger" and allow a corrective action plan as an intermediate step before a DEA license suspension is considered. HDMA members continue to have difficulty with DEA inspections/audits due, in large part, to not knowing what is required of the distributor to address "suspicious orders." Mr. Kelly also reported that Senator Joe Manchin (D-WV) continues to push S. 621 which calls for the rescheduling of hydrocodone combination products. In consideration of concerns raised by HDMA, the legislation would call for a three to five-year phase-in.

Ms. Anita Ducca (HDMA Vice President, Regulatory Affairs) reported that HDMA has submitted a list of questions to DEA seeking to gain a better understanding of what DEA requires of distributors. A meeting originally scheduled for July 31 with DEA officials was cancelled by the DEA. DEA has been referring to the industry compliance guidelines on suspicious orders in certain legal documents, resulting in the implication that it is "an industry standard." Since these guidelines were never intended to constitute a "standard," they have been taken down from the HDMA website, at the direction of the GPPC.

HDMA commented to DEA on the proposed take-back/disposal rule. The GPPC has recommended that HDMA consider a joint letter from the pharmacy and pharmaceutical associations calling on a coordinated federal effort with regard to the take-back/disposal issue. States and localities are also becoming more active in this area.

Mr. John Parker (HDMA Vice President, Communications) provided an update on the APCO Project designed to better understand the view of government officials, national influencers and the public regarding the distributor's role in addressing controlled substance abuse/diversion. Mr. Parker circulated the recent ad HDMA took out in *Politico* entitled "1-50-1" designed to brand the Association/industry's effort to obtain a federal 50-state solution to prescription drug and controlled substance issues. Mr. Parker presented the results of the preliminary opinion surveys conducted by APCO.

Mr. Gray reported that HDMA had several discussions with Rand & Co. regarding an independent assessment of the drug diversion issue. Rand was looking for a preliminary payment of $500,000 and appeared unwilling to grant HDMA any meaningful role in the study design, rejecting HDMA's suggested changes to the proposed agreement. The Rand study has been put on hold for the time being.

**2014**

2/27/14 Executive Committee Meeting:

Redacted

Mr. Kelly discussed other federal legislation currently pending as well as actions at the state level where bills to regulate pseudoephedrine and controlled substances as well as distributor/pharmacy thresholds are all pending.

The Drug Diversion/DEA Strategy Task Force met on December 11, 2013 and recommended the following actions:

1. Partner with other supply chain shareholder groups (including the Alliance to Prevent the Abuse of Medicines, the National Community Pharmacists Association, the National Association of Drug Diversion Investigators, the National Association of Boards of Pharmacy and the National Governors Association).

2. Develop specific policy recommendations, including potential solutions to the enforcement issues identified by HDMA (*see* pages Executive Committee Materials, Tab A, 29-32).

3. Engage in initial HDMA public relations branding.

Several members suggested HDMA continue requesting face-to-face meetings with DEA every quarter and to document those requests and responses. Staff will prepare a brief questionnaire for members to identify requests they have made over the past five years, along with responses. Individual company information will be kept confidential by outside counsel.

6/1/14 Board Meeting

Drug Abuse and Diversion. Mr. Kelly provided an overview of HDMA activity regarding drug abuse and diversion. There have been seven Congressional hearings in the past two months focusing on the issue with HDMA president, John Gray, testifying before the House Energy and Commerce Health Subcommittee. HDMA provided support for the Marino/Blackburn legislation, which has now been reintroduced as H.R. 4709 with two Democratic co-sponsors – Representative Welch (D-VT) and Representative Chu (D-CA).

Representative Marino had requested a meeting with U.S. Attorney General Holder scheduled to take place on June 9. Representatives from HDMA, NACDS, and NCPA will attend.

At the direction of a bipartisan group of Senators, the Government Accountability Office (GAO) is in the process of finalizing a survey to assess the effectiveness of the federal government, particularly DEA, in its effort to reduce prescription drug abuse. Mr. Kelly reported that the draft survey should be quite helpful in eliciting valuable responses from industry participants regarding the impact of DEA actions on the supply chain.

Mr. Kelly provided an update on the activities of the Alliance to Prevent Abuse of Medicine and the National Association of Boards of Pharmacy (NABP) Stakeholders Group.

DEA, acting upon a recommendation from HHS, proposed to "up-schedule" hydrocodone combination drug products from Schedule III to Schedule II. HDMA, in close consultation with members and outside counsel, filed extensive comments on the proposed rule requesting a 12 to 24-month implementation period for meeting the heightened physical security requirements.

6/1/14 Executive Committee Meeting:

Drug Abuse and Diversion. Mr. Kelly provided an overview of HDMA activity regarding drug abuse and diversion. There have been seven Congressional hearings in the past two months focusing on the issue with HDMA President, John Gray, testifying before the House Energy and Commerce Health Subcommittee. HDMA provided support for the Marino/Blackburn legislation. The Marino/Blackburn bill has been reintroduced with two Democratic co-sponsors – Representative Welch (D-VT) and Representative Chu (D-CA). Key elements, including provisions regarding corrective action plan and clear definition of terms, remain in the bill. Provisions requiring drug testing and background checks have been removed. The working group concept has been replaced with a joint report from FDA/CDC on federal efforts to address prescription drug abuse and the potential impact of these efforts on patients and supply chain entities.

Congressman Marino has requested a meeting with U.S. Attorney General Eric Holder, which is scheduled for June 9. Representatives from HDMA, NACDS, and the National Community Pharmacists Association (NCPA) will attend. A discussion ensued as to the appropriate representatives from HDMA. The matter will be further discussed with outside counsel, Linden Barber, Esq., who will be accompanying the industry groups.

At the direction of a bipartisan group of Senators, the Government Accountability Office (GAO) is in the process of finalizing a survey to assess the effectiveness of the federal government, particularly DEA, in its effort to reduce prescription drug abuse. Mr. Kelly reported that the draft survey should be quite helpful in eliciting valuable responses from industry participants in painting a picture of the impact of DEA actions on the supply chain.

9/29/14 Board of Directors Meeting:

Drug Abuse and Diversion. Mr. Kelly provided an update on legislative issues. H.R. 4709, the Marino/Blackburn bill, has passed the House. A companion bill, S.B. 2862 is pending in the Senate, and there is a slight chance of consideration and adoption in 2014. The Association continues in its efforts to schedule a meeting with the Assistant Attorney General to discuss drug abuse and diversion matters. Representatives Blackburn (R-TN) and Marino (R-PA have sent a letter to the Department of Justice seeking an investigation into inflammatory remarks made by DEA Deputy Administrator Rannazzisi. HDMA continues to work cooperatively with the Alliance to Prevent the Abuse of Medicines as well as the Pain Care Forum. There continues to be significant activity regarding controlled substances at the state level (Board Meeting Materials, Pages 48-51). DEA has issued its final rule regarding hydrocodone combination products granting only 45 days for industry to come into compliance. DEA has issued its final disposal/take-back rule. Individual members who have problems coming into compliance by October 6 should contact the DEA Regional Field Offices seeking dispensation.

9/28/14 Executive Committee Meeting:

Drug Abuse and Diversion. Mr. Kelly provided an update on legislative issues. H.R. 4709, the Marino/Blackburn bill, has passed the House. A companion bill, S.B. 2862 is pending in the Senate, and due to time limitations there is a slight chance of consideration and adoption in 2014. The Association continues in its efforts to schedule a meeting with the Assistant Attorney General to discuss drug abuse and diversion matters. Representatives Blackburn (R-TN) and Marino (R-PA have sent a letter to the Department of Justice seeking an investigation into inflammatory remarks made by DEA Deputy Administrator Rannazzisi. HDMA continues to work cooperatively with the Alliance to Prevent the Abuse of Medicines as well as the Pain Care Forum. There continues to be significant activity regarding controlled substances at the state level (Executive Committee Meeting Materials, Pages 48-49). DEA has

issued its final rule regarding hydrocodone combination products granting only 45 days for industry to come into compliance.

**2015**

6/7/15 Board of Directors Meeting:

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6/7/15 Executive Committee Meeting:

West Virginia Litigation. Mr. Gray and Mr. John Parker (HDMA Senior Vice President, Communications) provided background on litigation in West Virginia filed in 2012 against 13 distributors, 11 of whom are HDMA members. In essence, the lawsuit alleges that those distributors are improperly supplying controlled substances to West Virginia "pill mills," to the detriment of the state and legitimate patients who need controlled substances. Recent media reports have insinuated that distributors are responsible for controlled substance problems in West Virginia, including unlawful diversion and increased difficulty in getting controlled substances for legitimate uses. Ms. Janet Goss (GMMB) discussed how HDMA could engage the media to the industry's benefit, including a three-level strategy. Following discussion, there was general agreement that HDMA needs to engage the media. Toward that end, HDMA staff and GMMB will refine Level 1 (taking a strong, visible role in the passage of S. 483; engaging in proactive and reactive media outreach with other stakeholders in West Virginia to offer deep background briefings) and Level 2 (convening a public/private summit to address relevant issues with key stakeholders and reaching out to Sen. Manchin and staff) for further review by legal counsel of affected member companies. There was also general agreement that Level 3 (developing an HDMA-led pilot reporting program on drug distribution volume) may not be feasible or desirable.

9/28/15 Board of Directors Meeting:

Drug Abuse and Diversion. Mr. Patrick Kelly (HDMA Executive Vice President, Government Affairs) presented an update on the Association's principal policy issue – the ongoing problem of drug abuse and diversion. He noted the tension between the legitimate goals of stemming drug abuse and ensuring availability of legitimate, lawfully prescribed and needed drugs. The GAO Report (page 41) has been issued and highlights DEA's shortcomings and makes a number of recommendations, including better communication by DEA with the supply chain; additional guidance for suspicious orders monitoring and reporting; and enhanced input from pharmacists and associations representing pharmacies and pharmacists about guidance for pharmacists.

Mr. Kelly reported that H.R. 471, the Marino-Blackburn bill, passed the U.S. House of Representatives in April, and a similar bill, S. 483 (Hatch-Whitehouse), has been referred to the Judiciary Committee for consideration. The legislation would require a definition of "imminent danger" and provide more clarity and guidance regarding suspicious orders monitoring.

HDMA continues to work with the Alliance to Prevent the Abuse of Medicines and to participate in the National Medicine Abuse Awareness Month, October 2015. The Public Policy Council continues to engage the issue of the proper role of distributors in the prescription drug abuse epidemic. Mr. John Parker (HDMA Senior Vice President, Communications) and GMMB discussed possible communication and educational strategies.

President Gray noted that the HDMA Executive Committee had discussed and agreed to prioritize objectives on prescription drug abuse in the following order: 1.) exhaust all efforts to secure passage of S.483; 2.) continue to attempt to establish a productive dialogue with DEA; and, 3.) as needed, refresh existing policy and communications resources relating to industry efforts to combat prescription drug abuse and diversion. On the latter, the executive committee counseled against preparing any materials that could be construed as establishing industry standards or guidelines.

9/27/15 Executive Committee Meeting:

Drug Abuse and Diversion. Mr. Patrick Kelly (HDMA Executive Vice President, Government Affairs) provided an update on the Association's principal policy issue – the ongoing problem of drug abuse and diversion. He noted the tension between the legitimate goals of stemming drug abuse and ensuring availability of legitimate, lawfully prescribed and needed drugs. The GAO Report (page 41) has been issued and highlights DEA's shortcomings and makes a number of recommendations, including better communication by DEA with the supply chain; additional guidance for suspicious orders monitoring and reporting; and enhanced input from pharmacists and associations representing pharmacies and pharmacists about guidance for pharmacists.

Mr. Kelly reported that H.R. 471, the Marino-Blackburn bill, passed the U.S. House of Representatives in April, and a similar bill, S. 483 (Hatch-Whitehouse), has been referred to the Judiciary Committee for consideration. The legislation would require a definition of "imminent danger" and provide more clarity and guidance regarding suspicious orders monitoring.

HDMA continues to work with the Alliance to Prevent the Abuse of Medicines and to participate in the National Medicine Abuse Awareness Month, October 2015. The Public Policy Council continues to engage the issue of the proper role of distributors in

the prescription drug abuse epidemic. Mr. Parker and GMMC discussed possible communication and educational strategies.

Executive Committee Directive: Members of the executive committee suggested HDMA prioritize objectives on prescription drug abuse in the following order: 1.) exhaust all efforts to secure passage of S.483; 2.) continue to attempt to establish a productive dialogue with DEA; and, 3.) as needed, refresh existing policy and communications resources relating to industry efforts to combat prescription drug abuse and diversion. On the latter, the executive committee counseled against preparing any materials that could be construed as establishing industry standards or guidelines.

**2016**

2/18/16 Executive Committee Meeting:

West Virginia Litigation – HDMA filed an *amicus curiae* brief in the West Virginia Court of Appeals seeking to overturn the District Court's decision to deny defendant's Motion to Dismiss in an action where the West Virginia Attorney General has sued 14 out-of-state drug distributors for their roles in allegedly supplying controlled substances to "pill mills." The Court of Appeals, in a 3-2 Decision, upheld the lower court denial of the Motion to Dismiss and the case will go forward before the District Court. On February 3, 2016, Miami-Luken settled its part of the case.

In January 2016, the West Virginia Attorney General filed suit against McKesson for "failing to identify, detect, report, and help stop the flood of suspicious drug orders."

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DEA Acting Administrator Chuck Rosenberg and Office of Diversion Control Director Louis Milione have announced a series of meetings with supply chain representatives. Supply chain trade associations are scheduled to meet with DEA for a full day on February 29, 2016. Mr. Kelly circulated the draft agenda.

6/12/16 Board of Directors Meeting:

Drug Abuse and Diversion. Ms. Kristen Freitas (Vice President, Federal Government Affairs) presented a summary of Public Law No. 114-145, the "Ensuring Patient Access and Effective Drug Enforcement Act," effective April 19, 2016. She also discussed pending federal legislation. Mr. Patrick Kelly (Executive Vice President, Government Affairs) discussed the HDMA Public Policy Council's consideration of these issues, and possible next steps for HDMA in these areas.

6/12/16 Executive Committee Meeting:

Redacted

6/12/16 Board of Directors Meeting:

**GUEST SPEAKER LOUIS MILLIONE, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION**

Following an introduction by President and CEO John Gray, Mr. Millione, in prepared remarks, addressed the government's activities involving the diversion and abuse of prescription opioids, and the need for a meaningful, positive relationship between DEA and the distribution industry. DEA is working on an advanced notice of proposed rulemaking or a proposed rule on suspicious orders. DEA is also trying to achieve greater consistency across different field offices. Extensive discussion followed Mr. Millione's prepared remarks.

Following Mr. Millione's departure, the Board discussed HDMA's relationship with DEA. On a related matter, Mr. Gray reported that the Executive Committee had discussed whether and how HDMA should address negative media perceptions and misinformation regarding distributors and the abuse of prescription opioids. The concern is with ongoing West Virginia litigation as well as the possibility of similar

action by other states. The Executive Committee decided to reinstitute its Working Group to address this issue in the first instance, with a goal of having recommendations for its September 2016 meeting.

9/26/16 Board of Directors Meeting:

Drug Abuse and Diversion. Mr. Kelly provided an update. President Obama recently issued a proclamation on drug abuse, focusing principally on treatment. The U.S. Justice Department has announced that it is going to focus its enforcement efforts on doctors who are over-prescribing controlled substances. The Food and Drug Administration (FDA) is moving towards requiring black box warnings on these products. Congress recently enacted, and the President signed, S. 483, the Comprehensive Addiction and Prevention Act. HDA played a major role in shaping this law. The Drug Enforcement Administration (DEA) is working on a regulatory proposal for suspicious orders and has been more open to dialogue with HDA and its members. DEA has not yet begin the administrative process to implement S. 483, including the corrective action plan provision. There are a myriad of state bills dealing with taxing opioids as well as import/export and recordkeeping requirements.

**2017**

2/22/17 Executive Committee Meeting:

Drug Abuse and Diversion. Mr. John Parker (HDA Senior Vice President, Communications) provided an update on the highly inflammatory media environment regarding the role of wholesalers as well as the cases that have been brought in West Virginia. Mr. Robert Schooling (Reservoir Communications Group) discussed a proposal for the development and roll-out of a six-month Communications Program, explaining the role, in appropriate context, of the distributor.

Action: On motion duly made and seconded, $240,000 was approved for a six-month engagement of Reservoir Communications Group for message development and communications strategy.

6/11/17 Executive Committee Meeting:

PUBLIC RELATIONS CAMPAIGN AND INDUSTRY VALUE PROPOSITION. Mr. John Parker (HDA Senior Vice President, Communications) outlined the challenges faced by the pharmaceutical distribution industry with particular focus on prescription drug abuse. Challenges include activities at the federal, state and local levels and a significant amount of press attention. The Executive Committee had concluded that

distributors needed to better articulate their role in the supply chain and the efforts currently be undertaken to curtail prescription drug diversion and abuse.

Mr. Parker introduced Mr. Robert Schooling and Ms. Clare Krusing from Reservoir Communications Group who presented the results of their initial study into the best means of communicating the role of the prescription drug distributor in addressing prescription drug abuse.

Discussion ensued.

The Executive Committee generally supported recommendations 2 through 5 but noted additional time and clarification would be needed with respect to recommendation 1. The committee requested that Reservoir come back with a more specific document, including strategic options, as soon as possible.

6/11/17 Board of Directors Meeting:

Drug Abuse, Diversion and Value Proposition.

a. Policy Update. Mr. Kelly briefed the Board on recent legislative and legal activity in connection with the prescription drug abuse and diversion issues. The House of Representatives Energy and Commerce Committee has sent letters to manufacturers and distributors focusing on shipments to West Virginia. The Ohio Attorney General has brought lawsuits against manufacturers which have not yet involved distributors. The DEA remains quite active. Mr. Kelly provided an update on the *Miami-Luken* and *Masters* matters.

b. Public Relations Campaign. Mr. John Parker (HDA Senior Vice President, Communications) discussed efforts by HDA and its members to better communicate the role of distributors in the controlled substance supply chain and the efforts being undertaken by distributors to assist in reducing diversion and prescription drug abuse. Mr. Robert Schooling and Ms. Clare Krusing of Reservoir Communications Group reported on their study findings and set forth several recommendations for how HDA and its members could better put distributors' role in proper context. The Board agreed generally with a more proactive media relations campaign; more local engagement; thought leadership engagement; and better utilization of data in research. As to identifying specific solutions, the Board suggested that HDA work collaboratively with federal and state governments and other members of the supply chain to identify and implement solutions.

9/24/17 Executive Committee Meeting:

PUBLIC RELATIONS CAMPAIGN

Addressing Industry Reputation and Fighting Opioid Abuse. Mr. John Parker (HDA Senior Vice President, Communications) presented an update on activities since the Executive Committee's last meeting. Reservoir Communications' assistance in responding to stories about the opioid abuse epidemic and the role of supply chain members had been extended through the end of September. At its last meeting, the Executive Committee had agreed to consider a proposal from Reservoir for HDA to accelerate its media, partnership, and communications programs to place the role of the distributor in proper perspective and to assist/lead the supply chain in fighting opioid abuse.

Mr. Robert Schooling (Founder and President, Reservoir Communications Group) presented a proposal entitled "Delivering Solutions: Industry Reputation and Opioid Abuse." He recommended a solutions-based platform that included common sense solutions. He introduced the concept of RDRx (Reduce Dispose Rx). The program would include both national and targeted state initiatives.

Discussion ensued. There was widespread agreement that the industry needs to undertake this type of program with HDA leadership.

Action: On motion duly made and seconded, the Executive Committee recommended that the Board consider and approve the following motion:

1. HDA should take a more proactive/leadership role in developing and implementing a communications program to address the opioid abuse crisis;

2. The message should be reviewed and, if necessary, revised to capture the plan of the distribution chain as led by HDA;

3. Other members of the distribution chain, particularly at the dispensing and prescribing levels, should be approached to partner with HDA in sponsoring and disseminating the message;

4. HDA should commit to fund this communications program. The funding for 2018 will be determined by the Executive Committee in early October. Funding for future years will be determined on an annual basis;

5. A timeline will be established for how HDA will move forward with the Reservoir proposal;

6. Reservoir should be retained as the communications vendor;

7. The Executive Committee as a whole will act as the Steering Committee for the Program.

9/25/17 Board of Directors Meeting:

Drug Abuse/Diversion.

Policy Update. Mr. Kelly presented an update on policy issues surrounding the drug abuse/diversion issue, including the legislative strategy proposal from the Public Policy Council. As background, he discussed the decisions in the *Masters* litigation and Mallinckrodt settlement. He also discussed: HDA comments to the Department of Justice concerning regulatory reform with focus on suspicious order monitoring; meeting with DEA to discuss SOM and communications with industry; and FDA legislative efforts to better address the opioid abuse.

The Public Policy Council proposed a three-part legislative strategy, including:

i. Develop a proactive legislative strategy to address drug abuse and legislation;
ii. Work closely with colleague supply chain organizations to advocate for solutions; and
iii. Establish a Coordinating Committee to oversee these activities.

Action: On motion duly made and seconded, the Board approved the legislative strategy proposal of the Public Policy Council.